K003682

JAN 26 2001

510(k) SUMMARY

A. Submitter Information:

Submitter:	MEDCOMP® 1499 Delp Drive Harleysville, PA 19438 (215) 256-4201 Telephone (215) 256-1787 Fax
Contact:	Jeanne M. Cush
Date Prepared:	November 12, 2000

B. Trade Name: Medcomp Z-Cath

Common Name: Catheter, Intravascular, Therapeutic, Long-Term

Classification: LJS

C.F.R. Section: 880.5200 5170

C. Predicate Device: K953811 Medcomp P-Cath

D. Device Description:

The Medcomp Z-Cath Catheters are designed for peripheral vein catheterization. The Z-Cath lumen is comprised of a soft radiopaque polyurethane material. The lumen is connected to the extensions via a soft pliable hub with suture wing for secure placement. Clamps are provided on the extension tubes to prevent air/fluid communication. Female luer connectors provide the connection for intravenous administration.

The catheters are available in 4F and 5F single lumen versions, and 5F and 6F double lumen versions. All versions are 60cm long with depth markings in 5cm increments.

The Z-Cath product line is packaged with the necessary accessories to facilitate catheter insertion.

E. Intended Use:

The Medcomp Z-Cath Catheters are designed for long-term central venous catheterization or prolonged intravenous administration of fluids, medications, and / or when nutritional therapy is prescribed.

This catheter may be inserted via the basilic or cephalic vein.

F. Comparison to Predicate Device:

The Z-Cath is substantially equivalent to the predicate device in terms of intended use, anatomical location, design, performance, labeling, manufacturing process and method of sterilization.

The differences between the Z-Cath and the predicate device are duration of use, material formulation and method of insertion. The predicate device is intended for short-term access, where the Z-Cath is indicated for long-term. Although both catheters are manufactured from polyurethane, the material formulations are different. The Z-Cath is designed to be inserted over a guidewire, while the predicate device is not.

G. Performance Data:

The following in-vitro testing was performed on the Medcomp Z-Cath to assure reliable design and performance in accordance with ISO 10555-1 and 10555-3.

- Force at Break
- Air Leakage
- Liquid Leakage
- Elongation
- Gravity Flow Rate

Biocompatibility testing on the Z-Cath Catheters demonstrates the materials used meet the requirements of ISO 10993 for a permanent contact device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 26 2001

Ms. Jeanne M. Cush
Senior Regulatory Affairs Associate
Medical Components, Incorporated
1499 Delp Drive
Harleysville, Pennsylvania 19438

Re: K003682
Trade Name: Medcomp Z-Cath
Regulatory Class: II
Product Code: LJS
Dated: November 12, 2000
Received: November 30, 2000

Dear Ms. Cush:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K003682

Device Name: Medcomp Z-Cath Catheter

Indications for use:

The Medcomp Z-Cath Catheters are designed for central venous catheterization or prolonged intravenous administration of fluids, medications, blood sampling and/or when nutritional therapy is prescribed.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003682